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No. 95-737

IN THE
**Supreme Court Of The United States**
October Term, 1995

ROYCE LABORATORIES, INC.
*Petitioner,*

v.

BRISTOL-MYERS SQUIBB COMPANY,
AND E.R. SQUIBB & SONS, INC.,
*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court Of Appeals for the Federal Circuit**

# BRIEF IN OPPOSITION

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## QUESTIONS PRESENTED

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417) ("Hatch-Waxman Act") governs the filing and approval of abbreviated new drug applications ("ANDAs") to market generic versions of previously approved new drugs and provides that it is an act of infringement to file an ANDA seeking approval by the Food and Drug Administration to market a generic drug product prior to the expiration of any patent which covers that drug. 35 U.S.C. § 271(e)(2). The exclusive remedies for such acts of infringement are provided in 35 U.S.C. § 271(e)(4), including an order that the "effective date of any [FDA] approval of the drug . . . [shall] be a date which is not earlier than the date of the expiration of the patent that has been infringed." 35 U.S.C. § 271(e)(4)(A).

The Uruguay Round Agreements Act ("URAA"), Pub. L. No. 103-465, 108 Stat. 4809 (codified in part at 35 U.S.C. § 154(c) (West Supp. 1995), enacted December 8, 1994, 21 U.S.C. § 154(c)(2), (3)), redefined the terms of various patents and limited certain remedies available to patentees. The transition provision of the URAA states:

> (2) REMEDIES. The remedies of sections 283, 284, and 285 of this title [35 U.S.C.A.] shall not apply to Acts which --
>
> (A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act [June 8, 1995]; and
>
> (B) became infringing by reason of paragraph (1) [the redefined expiration date].

> (3) REMUNERATION. The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2) of this title [35 U.S.C.].

The questions presented by the Petition are:

1. Does the transition provision of the URAA, which refers only to the remedies of 35 U.S.C. §§ 283, 284 and 285, abrogate the remedy provided by 35 U.S.C. § 271(e)(4)(A) for an act of infringement under 35 U.S.C. § 271(e)(2)?

2. Does the transition provision of the URAA render certain acts committed during the transition period non-infringing, or only limit certain remedies that are available to the patentee for acts that are infringing?

## PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this Brief in Opposition.

## LIST OF PARTIES PURSUANT TO RULE 29.6

Bristol-Myers Squibb Company has no parent corporation. E.R. Squibb & Sons, Inc. is a wholly-owned subsidiary of Bristol-Myers Squibb. Set forth below is a list of non-wholly owned subsidiaries of Bristol-Myers Squibb Company.

Bristol-Myers Lion Ltd. (Japan)
Bristol-Myers S.A. (France)
Bristol-Myers Squibb G.m.b.h. (Germany)
Bristol-Myers Squibb Korea Limited (Korea)
Mead Johnson (Guangzhou) Ltd. (China)
P.T. Squibb Indonesia (Indonesia)
Squibb of Bangladesh Limited (Pakistan)
Synbiotics Limited (India)
Instituto Bio-Medico S.A. de C.V. (Mexico)
Laboratories UPSA SAS (France)
Myagen (France)
RCS Realty Corporation (Philippines)
Servicios Bio-Medicos de Compresion S.A. (Mexico)
Sino American Shanghai Squibb Pharma Ltd. (China)
SMI Bristol Limited (Japan)
Squibb Nigeria Limited (Nigeria)
UPSA Investissements (France)
2309 Realty Corporation (Philippines)

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**On Petition for a Writ of Certiorari to the United States Court Of Appeals for the Federal Circuit**

## BRIEF IN OPPOSITION

Bristol-Myers Squibb Company and E.R. Squibb & Sons, Inc. (collectively "Bristol") file this brief in Opposition to the Petition for a Writ of Certiorari filed by Petitioner, Royce Laboratories, Inc. ("Royce").

## OPINIONS BELOW

The opinion of the Court of Appeals is reported at 36 U.S.P.Q. 2d 1641 (Fed. Cir. 1995) and is reproduced in the Appendix to the petition, beginning at page A-1. The opinion of the district court is reported at 36 U.S.P.Q. 2d (BNA) 1637 (S.D.Fla. 1995) and is reproduced, along with the district court order, in the Appendix to the petition, beginning at page A-27.

## JURISDICTION

The judgment of the Court of Appeals was entered on November 1, 1995. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1) (1988). The jurisdiction of the district court rested on 28 U.S.C. § 1338(a) (1988).

## COUNTERSTATEMENT OF THE CASE

The dispute between the parties concerns Royce's attempt to obtain approval by the Food and Drug Administration ("FDA") to market a generic version of a patented prescription pharmaceutical product (captopril) made by Bristol *prior* to the expiration date of Bristol's patent covering that product. Royce did so by amending its abbreviated new drug application ("ANDA") with the FDA to contain a certification that Bristol's patent was invalid or unenforceable. Under the Hatch-Waxman Act, this is an act of patent infringement.

There is no dispute that Bristol's patent is valid and that it covers Royce's generic drug product. Royce's only "defense" to its admitted act of infringement is the claim that the recently enacted Uruguay Round Agreements Act ("URAA") provides it with a "statutory license" to market captopril prior to expiration of Bristol's patent. A panel of the Federal Circuit held that the URAA did not do so. A

different panel of the Federal Circuit had previously reached the same conclusion in another case involving Bristol's captopril patent brought by two other generic drug companies. *See DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed Cir. 1995). Neither of the plaintiffs in that case sought review by this Court.

The decisions by these two different panels of the Federal Circuit are consistent with an FDA policy decision issued May 25, 1995. There has been no judicial challenge to the FDA policy.

### A. The Statutory Framework

The legal issue decided below concerns the relationship between the provisions of the URAA and the Hatch-Waxman Act.

#### 1. The Hatch-Waxman Act

The Hatch-Waxman Act introduced provisions to both the Patent Code and the Food Drug and Cosmetic Act to govern the filing, approval and effective date of approval of ANDAs which seek approval by FDA to market generic versions of previously approved new ("pioneer") drugs.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer seeking approval to market a generic version of a patented drug may submit to FDA an abbreviated new drug application (ANDA).[1] 21 U.S.C. § 355(j) (1994). As part of the ANDA process, when the patent has not expired, the generic drug manufacturer must certify either the "date on which [the] patent will expire" (a paragraph III

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[1] An ANDA permits a generic manufacturer to rely on the data that research-based companies generated at great time and expense to develop and secure original FDA approval of the drug.

certification) or that the patent is "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug for which the [ANDA] is submitted" (a paragraph IV certification). 21 U.S.C. § 355(j)(2)(A)(vii)(III), (IV).

If an ANDA contains a paragraph IV certification, the ANDA applicant must give notice to the patentee and must provide detailed bases for its belief that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B)(i). The patentee then has 45 days to sue the ANDA applicant for infringement. 21 U.S.C. § 355(j)(4)(B)(iii). If the patentee files suit within that period, then FDA approval does not occur until expiration of the patent, judicial resolution of the infringement suit, or thirty months from the patentee's receipt of notice, whichever is earliest. *Id.*

The Hatch-Waxman Act also added provisions to the Patent Code that relate specifically to the generic drug approval process. Section 271(e)(2) states that it shall be an act of infringement to submit an ANDA "if the purpose of such submission is to obtain approval under [the FD&C Act] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."[2] 35 U.S.C. § 271(e)(2). Section 271(e)(4) lists the remedies available for infringement under section 271(e)(2), and states that these are the "only remedies" for such an act of infringement. One of these remedies is an order that the "effective date of any [FDA] approval of the drug . . . be a date which is not earlier than the date of the expiration of the patent that has been infringed." 35 U.S.C. § 271(e)(4)(A). The remedy of section 271(e)(4)(A) is specifically identified as one of the remedies which a court may order in an action by the patentee in response to a paragraph IV certification. *See* 21 U.S.C. § 355(j)(4)(B)(iii).

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2 Section 271(e)(1) establishes that it is not an act of infringement to use a patented drug solely for purposes related to obtaining regulatory approval of the product. 35 U.S.C. § 271(e)(1).

## 2. The URAA

The URAA was enacted in December 1994 to implement the Uruguay Round Agreements, a series of multilateral trade agreements, which includes the General Agreement on Tariffs and Trade (GATT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

URAA's provisions amend Title 35 of the U.S. Code to redefine the period of patent protection for some patents. Section 532(a)(1) of the URAA provides, *inter alia*, that, for patents in force on June 8, 1995, or that result from an application filed before that date, the patent term shall be the greater of 17 years from the granting of the patent or 20 years from the date on which the application for the patent was filed, or under certain circumstances 20 years from the date of the earliest patent application filing.

The URAA contains a transitional provision governing acts that will become infringing due to the extension of patents in effect or already filed as of June 8, 1995. While both Royce and *amici* characterize this provision as a "statutory license," section 532(a)(1) of the URAA merely limits the availability of certain specific statutory patent infringement remedies for acts that were commenced, or for which substantial investment was made, before June 8, 1995, and which become infringing because of the extension of the patent period.

Thus, section 532(a)(1) provides that the remedies set out in sections 283, 284, and 285 of Title 35 (which provide for injunctions, damages, and attorney and fees) will not apply to infringing acts during this period.[3] In lieu of those

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3 Section 532 of the URAA provides:

> (c) CONTINUATION . . .
>
> (2) REMEDIES. The remedies of sections 283, 284, and 285 of this title [35 U.S.C.] shall not apply to Acts which --

remedies, the statute provides for payment of "equitable remuneration." The transition provision of URAA does not refer to or limit the remedies set out in section 271(e)(4).[4] The Hatch-Waxman Act provides that these are the "only remedies" available for the act of infringement at issue in this case, *i.e.*, infringement under section 271(e)(2). 35 U.S.C. § 271(e)(4).

### 3. FDA Policy Decision

The effect of URAA's redefined patent terms on the ANDA process was the subject of a notice and comment proceeding conducted by the FDA in which representatives of all segments of the pharmaceutical industry, including

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> (A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act [June 8, 1995]; and
>
> (B) became infringing by reason of paragraph (1) [the redefined expiration date].
>
> (3) REMUNERATION. The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this tile [35 U.S.C.A.].
>
> URAA, Pub. L. No. 103-465, 108 Stat. 4809, 4984-85 (codified at 35 U.S.C.A. § 154(c)(West Supp. 1995)).

[4] Congress was clearly aware of these provisions when enacted the URAA since, as the FDA has recognized, they are amended by other provisions of the URAA, albeit in ways not relevant here. *See* App.-14. In this regard, the URAA provides that: "Nothing in this Act shall be construed . . . to amend or modify any law of the United States, including any law relating to--(I) the protection of human, animal or plant life or health, . . . unless specifically provided for in this Act." Section 102(a)(2).

both generic and pioneer companies, submitted comments. In a May 1995 letter, the FDA issued its decision on this issue, concluding that the URAA provisions do not affect acts of infringement under 35 U.S.C. § 271(e)(2) or the remedies for that act of infringement under 35 U.S.C. § 271(e)(4). *See* Appendix ("App.").

Despite its expressed desire to do so, the FDA "[could] not find a basis for adopting the interpretation of the URAA that 35 U.S.C. 154, as amended, applies to infringements through ANDA submissions, which are governed by 35 U.S.C. 271(e)." App. 13-14. The FDA recognized that "the URAA is not 'silent or ambiguous' on the question of applying the transitional provision to the generic drug approval process." App. 13. Applying the "plain language" of the transitional provision of the URAA, FDA concluded that this provision simply "limits the remedies available to a patentee in a suit brought against an infringer whose actions became infringing due to the URAA patent extension." App. 14. In support of its conclusion, the FDA observed that the URAA's transition provision specifically lists the three remedial provisions that are unavailable, *i.e.*, 35 U.S.C. 283, 284, and 285, but "does not list among the unavailable remedies section 271(e)(4), which provides for injunctions, damages, and attorney fees for infringement actions arising from a manufacturer seeking approval from FDA to market a generic version of a patented drug product before the patent on the product expires." App. 14. Responding to arguments by generic pharmaceutical manufacturers that this was an inadvertent legislative oversight, the FDA noted that this "is not an example of Congress having overlooked a statutory provision it might have changed had it been aware of its existence," since the URAA made other amendments to section 271(e)(4). App. 14.

Respondents are aware of no court challenge to the FDA policy decision.

### B. The Captopril Patent

Bristol owns United States Patent 4,105,776 (the "captopril patent"), which discloses and claims the chemical compound having the generic name "captopril." Captopril was developed, and marketed by Bristol under the trademark Capoten®, for the treatment of hypertension, heart failure, diabetic nephropathy, and left ventricular dysfunction following myocardial infarction. The compound is the first marketed compound in a class of drugs known as angiotensin converting enzyme ("ACE") inhibitors. When it issued on August 8, 1978, the expiration date of the captopril patent was August 8, 1995. Under the URAA, the expiration date of United States Patent 4,105,776 is now February 13, 1996.

### C. The DuPont-Merck Case

The instant case was preceded by another court proceeding involving Bristol's captopril patent. *DuPont Merck v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995). Two generic drug manufacturers sued Bristol, contending that the URAA transition provision gave them a "license" or "authority" to market captopril prior to the redefined term of the captopril patent if they paid "equitable remuneration" to Bristol.

The district court dismissed plaintiffs' declaratory judgment action for lack of jurisdiction, holding that there was no "actual case or controversy" because the two generic manufacturers had not amended their ANDAs to include paragraph IV certifications challenging the validity, infringement or enforceability of Bristol's captopril patent.

On appeal, the Federal Circuit found that there was jurisdiction. Rather than remand, however, the court of appeals proceeded to resolve "the merits of the dispute," holding that the generic companies have not stated a claim "upon which relief may be granted" and "are not entitled to

relief as a matter of law." 62 F.3d at 1402. Applying the plain language of the URAA, the court of appeals held:

> In sum, the URAA, by its terms, exempts a qualified infringer from the remedies of sections 283, 284, and 285 of Title 35. The URAA, however, works no change on the definition of infringement under section 271(e)(2) and has no affect on the statutory provisions relating to FDA approval of ANDAs that are triggered by that act of infringement. *See* 21 U.S.C. § 355(j).

*Id.* A petition for rehearing was denied on August 28, 1995. Plaintiffs did not seek review by this Court.

### D. The Dispute Between the Parties

#### 1. Royce's ANDA

Royce filed an ANDA seeking approval to market a generic version of captopril. As originally filed, Royce's application contained a paragraph III certification stating that the captopril patent expired on August 8, 1995. After the enactment of URAA, that certification was no longer accurate, and FDA could not lawfully approve Royce's ANDA. Consequently, Royce amended its ANDA by eliminating the paragraph III patent certification and substituting a paragraph IV certification.

As required by the Hatch-Waxman Act, Royce notified Bristol of the paragraph IV certification. Royce did not (and does not) contend that the captopril patent was invalid or that the claims of the patent did not cover Royce's generic captopril product. The sole basis of Royce's "opinion" that the patent will not be infringed is its

contention that the transition provision of the URAA gives Royce a "statutory license" to market captopril during the period August 8, 1995 to February 13, 1996 because Royce had made a "substantial investment" in anticipation of marketing captopril and Royce will pay Bristol "equitable remuneration."

### 2. The District Court Proceedings

Bristol filed suit against Royce in the United States District Court for the Southern District of Florida, alleging that Royce had infringed Bristol's captopril patent in violation of 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA seeking FDA approval to market a generic version of captopril before the expiration of Bristol's patent. Bristol alleged that Royce's paragraph IV certification was "insufficient and inadequate on its face, and inconsistent with applicable law."

Bristol sought judgment that (i) the captopril patent is valid and has been infringed by Royce and (ii) the court enter an order pursuant to 35 U.S.C.A. § 271(e)(4)(A) that the effective date of any FDA approval of Royce's ANDA under 21 U.S.C. § 355(j)(4)(B) be a date not earlier than the February 13, 1996 expiration date of the captopril patent.

One week after the complaint was filed, Royce filed an emergency motion "To Set Aside The Injunction Delaying The Food And Drug Administration's Approval Of Defendant's Abbreviated New Drug Application And To Dismiss The Complaint." In support of its motion, Royce reiterated the contentions contained in its paragraph IV notice to Bristol, and submitted a declaration of its president, averring that Royce had spent over $1 million in connection with the preparation and filing of its ANDA.

Bristol opposed Royce's motion to dismiss on two grounds. *First*, as a matter of law, the URAA does not abrogate the remedies of section 271(e)(4) that result from a section 271(e)(2) act of infringement. *Second*, even if the

URAA provides a "statutory license" of the sort claimed by Royce, there was no way to ascertain whether Royce satisfied the factual predicate of a "substantial investment" on a motion to dismiss because it required discovery and an evidentiary hearing.

On August 24, 1995 (without permitting any discovery on the factual issues in dispute), the district court issued an order granting Royce's motion to dismiss and dissolving the statutory stay on FDA approving Royce's ANDA.[5] Although the district court found that Royce had committed the act of infringement under 35 U.S.C. § 271(e)(2) alleged in the complaint (*i.e.*, filing an ANDA seeking FDA approval to market a generic drug product prior to the expiration of the captopril patent), it held that this act of infringement was not actionable because the "safe harbor" provision of URAA made the ultimate commercial manufacture and marketing of captopril non-infringing.[6]

Bristol appealed.

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[5] However, the District Court refused to order the FDA to make approval of Royce's ANDA immediately effective. A-39.

[6] On the basis of the untested, conclusory assertion in an affidavit submitted by Royce in support of its motion to dismiss, the district court then found that Royce satisfied the URAA requirement of "substantial investment" made prior to June 8, 1995. A-37. Although it recognized that Bristol contested the factual and legal adequacy of Royce's claimed investment and sought discovery and an evidentiary hearing on this issue, the district court (in a footnote) concluded that Royce had, in fact, made a $1 million investment, and that, as a matter of law, this constituted a "substantial investment" within the meaning of the URAA. *Id.* The district court ruled that Bristol therefore had no cause of action other than a claim for "equitable remuneration." *Id.*

### 3. The Decision Below

The Federal Circuit reversed the decision of the district court.[7]

The court of appeals first examined the application of the Hatch-Waxman Act requirements to Royce's ANDA in the absence of the URAA. Applying this Court's decision in *Eli Lilly Co. v. Medtronics, Inc.*, 496 U.S. 661 (1990), the court of appeals stated that, in an action for patent infringement under section 271(e)(2)(A), the court must "determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent." A-12 (emphasis in original). The court recognized that if "the patent is not invalid and the infringement would occur," the ANDA applicant's paragraph IV certification is incorrect and the patentee is entitled to an order that FDA approval of the ANDA cannot be made effective prior to expiration of the patent. Since Royce did not allege that the captopril patent is invalid or that its claims did not cover Royce's generic captopril product, the court of appeals found that (in the absence of the URAA), Royce would infringe Bristol's patent if it marketed captopril prior to the February 13, 1996 expiration date of the patent. A-13.

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[7] While Bristol's Federal Circuit appeal was pending, Royce filed a petition with the United States Court of Appeals for the Eleventh Circuit, challenging the validity of an FDA regulation, 21 C.F.R. § 314.307(e)(1995), which provides that FDA approval of an ANDA which challenges the validity, enforceability of infringement of a patent will be made effective on the date of an appellate decision that the patent is invalid, unenforceable or not infringed. The reasons for this Rule were set out at length in Federal Register notices proposing and adopting the regulation. *See* 54 Fed. Reg. 28,872, 28,894-95 (July 10, 1989); 57 Fed. Reg. 50,338, 50,353 (Oct. 3, 1994). Relying on the decision of the district court in this case, Royce asked the Eleventh Circuit to order the FDA to make its ANDA effective immediately -- relief that the district court had refused to provide. Following the decision of the Federal Circuit, Royce's petition was dismissed as moot on December 2, 1995.

The court then proceeded to determine whether the URAA altered this conclusion. Examining the language of the URAA transition provision, 35 U.S.C. § 154(c), the court found that the URAA does not make "infringing conduct non-infringing during the Delta period." A-15. After noting that the plain language of the URAA merely limits remedies for certain types of infringing conduct, *i.e.*, the remedies of 35 U.S.C.A. §§ 283, 284 and 285, the court recognized that "the URAA makes no mention of the provisions of the Hatch-Waxman Act," including the provisions for acts of infringement under section 271(e)(2) and the remedies that are available to the patentee under 35 U.S.C. section 271(e)(4) based on that act of infringement. As did the FDA before it, the court pointed out that, if Congress had intended to alter the Hatch-Waxman Act's "finely crafted ANDA approval process, in the manner urged by Royce, at the very least it would have referred to 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e). . . ." A-16-17.

Accordingly, the court held that the URAA "does not convert Royce's sale of generic captopril during the Delta period into a non-infringing activity." A-19. As a result, Royce's paragraph IV certification to the contrary was incorrect, entitling Bristol to the remedy of section 271(e)(4)(A).

The court did not reach the alternate ground for reversal urged by Bristol based on the district court's improper resolution of factual issues on Royce's motion to dismiss..

After filing its Petition for Writ of Certiorari (and a motion for expedited consideration) in this Court, Royce filed a petition for rehearing with the Federal Circuit. On December 8, 1995, the petition for rehearing was denied.

## REASONS FOR DENYING CERTIORARI

The petition should be denied because the decision of the Court of Appeals below is correct, does not conflict with

any decision of this Court or any other court of appeals and does not present an important question for resolution by this Court.

## I. THE DECISION BELOW IS CORRECT AND DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT OR ANY COURT OF APPEALS

The court of appeals carefully considered and rejected the arguments raised here by petitioner. There is no conflict between the decision below and the decision of any other court of appeals or this Court. To the contrary, this was the *second* time that a panel of the Federal Circuit reached the same conclusion in a case with respect to Bristol's captopril patent. The decision below was correct and fully in accordance with applicable Supreme Court precedent, the plain meaning of the statutes involved and the policy of the FDA, *viz.* the federal agency with specific statutory responsibility for administering the Hatch-Waxman Act.

### A. There Is No Conflict with Any Decision of This Court

The Petition contends that the decision below conflicts with the decision of this Court in *Eli Lilly Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). Pet. at 25. That is not so.

In the first place, the *Eli Lilly* case did not address the interrelationship between the URAA and the Hatch-Waxman Act which was the subject of the decision below. Rather, *Eli Lilly* dealt with the issue of whether certain of the patent provisions of the Hatch-Waxman Act (35 U.S.C. § 271(e)(1)) applied to medical devices.

Moreover, the decision below is completely in accord with this Court's decision in *Eli Lilly*. The lower court

specifically cited *Eli Lilly* and applied the method for evaluating the act of patent infringement under 35 U.S.C. § 271(e)(2) that is set out in the Court's opinion in *Eli Lilly*. Contrary to the suggestion of the Petition, the lower court did *not* conclude that the mere filing of a paragraph IV certification entitled Bristol to the relief it sought. Rather, the lower court looked to see whether the ANDA applicant's paragraph IV certification was correct, *i.e.*, whether the patent at issue is valid and, if so, whether sale of the generic product at issue infringed that patent. This was the very analysis that Royce asked the court to apply on the basis of *Eli Lilly*. A-11.

Furthermore, the lower court properly recognized that if, in enacting the URAA, Congress had meant to alter the delicate balance of provisions in the Hatch-Waxman Act, as described by this Court in *Eli Lilly*, it would have done so explicitly and not by implication, as Royce suggests. App. - 16-17. The lower court cited *Eli Lilly* for the indisputable proposition that the provisions of the Hatch-Waxman Act created "an important new mechanism designed to guard against infringement of patents relating to pioneer drugs" with enforcement provisions that "apply only to drugs and not to other products." 496 U.S. at 676-79. App. - 16.

In short, there is no conflict whatsoever between the decision below and this Court's decision in *Eli Lilly*, and certainly no irreconcilable "conflict" of the sort that might support review by this Court. *See, e.g., Layne & Bowler v. Western Well Works, Inc.*, 261 U.S. 387, 393 (1923).

### B. The Decision Below Does Not Conflict with Any Other Court of Appeals Decisions

Although Royce suggests that the issues raised in the petition are novel, they have been previously considered in several different forums, with consistent results. As a result,

review by this court is not necessary to reconcile conflicting appellate or administrative decisions.

The decision of the lower court is the second decision by a panel of the Federal Circuit which has rejected the contention that the URAA grants a "license" to generic drug manufacturers to market captopril prior to the expiration of Bristol's admittedly valid patent. Thus, in *DuPont Merck* (cited in the decision below), a *different* panel of the Federal Circuit rejected the claims of two other generic drug companies that the URAA gave them a right to market captopril before expiration of the captopril patent, as redefined by the URAA. Far from a conflict, there is complete accord between the only two pertinent appellate decisions on this issue.

Nor does the decision below conflict with any administrative policy or interpretation of the Food and Drug Administration -- the administrative agency with statutory responsibility for implementing the ANDA process established by the Hatch-Waxman Act. To the contrary, the FDA specifically concluded that the URAA does not affect the remedies available for acts of infringement under section 271(e)(2). That is also what the lower court found. There has been no court challenge to FDA's policy, and there is no conflict between that policy and the decision below. *Compare Morton v. Ruiz*, 415 U.S. 199, 201-02 (1974) (decision below asserted to be "inconsistent with long-established policy of the Secretary [of the Interior] and of the Bureau").

### C. The Decision Below Correctly Applies the Plain Language of the Statute

In an effort to secure review by this Court, both Royce and *amici* ignore the actual language used by Congress in enacting the URAA and misstate the decision of the lower court.

*First*, contrary to the Petition's repeated reference to the "statutory license" of the URAA, the URAA does not provide anyone, including an ANDA applicant, a "license" to market any product.[8] Nor does the URAA make any conduct "non-infringing". Rather, its plain language applies only to acts which are infringing. Thus, section 154(c)(2)(B) specifically states that it applies only to:

"Acts which --

(B) become *infringing* by reason of . . . ."

35 U.S.C. § 154(c)(2)(B)(emphasis added). When Congress wishes to make acts non-infringing, it knows how to do so in clear and unmistakable terms, as Congress did in the Hatch-Waxman Act when it added section 271(e)(1), which stated: "It shall not be an act of infringement . . . ." 35 U.S.C. § 271(e)(1).

Instead, as is clear from the plain language of the statute, and as the FDA and two different panels of the Federal Circuit have uniformly found, the transition provision of the URAA simply limits certain *remedies* available to certain patent holders in certain types of patent infringement actions. The remedies that "shall not apply" are specifically identified as the "remedies of Sections 283, 284 and 285" of the Patent Code. Clearly, 35 U.S.C. § 154(c) has no impact on an action to redress infringement under 35 U.S.C. § 271(e)(2), the remedies for which are provided by 35 U.S.C. § 271(e)(4). This includes the remedy of section 271(e)(4)(A) which Royce seeks to avoid, *i.e.*, an order that the effective date of ANDA approval be "a date which is not earlier than the date of the expiration of the patent which has been infringed . . . ."

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[8] The URAA nowhere uses the term "license." As the statutes which Royce cited below make clear, Congress knows how to grant a "license" in clear and unmistakable terms when it wishes to do so. *See, e.g.*, 42 U.S.C. § 2183(b)(2) (1988) ("the Commission shall grant such patent license . . ."); 42 U.S.C. § 7608 (1988) (". . . issue an order requiring the person who owns such patent to license it . . .").

*Second*, Royce and *amici* distort the holding of the lower court, contending that the decision "converts the paragraph IV procedure into a trap which prevents otherwise qualified parties from invoking a statutory license such as that found in the URAA." Pet. at 22. Petitioner suggests that the lower court held that the mere filing of a Paragraph IV certification is an act of infringement sufficient to justify an order that the FDA cannot approve an ANDA prior to the expiration of an applicable patent, whether or not the patent was valid and whether or not it will actually be infringed.

That is simply *not* what the lower court held. To the contrary, the Federal Circuit specifically found that once a Paragraph IV certification is filed, the court must

> determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent. If the court determines that the patent is not invalid and that infringement *would* occur, and that therefore the ANDA applicant's paragraph IV certification is incorrect, the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires.

A-12-13 (emphasis in original). Far from creating a Catch-22 procedural trap, the lower court's decision specifically endorses the need for the very review Royce contends is required.[9]

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9 Here, there is no dispute that Bristol's patent is valid and that it covers Petitioner's generic captopril product. Under the circumstances, it is indisputable that Royce will infringe Bristol's patent if it markets captopril before expiration of the patent. Indeed, the very provision of the URAA on which Royce relies for its alleged "license" confirms that marketing by Royce would infringe Bristol's patent because it specifically relates only to acts that are (or become) "infringing."

The lower court held (correctly) that the "safe harbor" provision of the URAA simply eliminated the remedies of sections 283, 284 and 285 in certain cases. It did not take away the *separate* remedies of section 271(e)(4) which are available to the patentee for an act of infringement under section 271(e)(2) (admitted here) of seeking FDA approval to market a generic product prior to the expiration of a patent.[10] When Congress wishes to take away all remedies, it says so in explicit terms. *Compare* 35 U.S.C. § 287(a) ("no damages shall be recovered"); 35 U.S.C. § 287(b)(2) ("no remedies for infringement . . . shall be available"); 35 U.S.C.A. § 271(g) ("no remedy may be granted"). It did not do so here.

Contrary to the suggestion of Royce and *amici*, there is nothing unusual or puzzling about the fact that Congress did not alter the provisions of the Hatch-Waxman Act. Doing so would have disturbed the delicate balance between the interests of generic and pioneer pharmaceutical companies that are reflected in the Hatch-Waxman Act which created a new and self-contained section -- Section 271(e) -- of the Patent Code.[11] The Hatch-Waxman Act confers on generic drug companies an immunity from infringement given to no other industry -- the freedom to use a patented invention without liability or having to pay compensation in order to develop ANDA applications. If

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[10] The remedies of sections 283, 284 and 285 have no application to the generic drug approval process. "The remedies prescribed by subparagraphs (a), (b) and (c) [of § 271(e)(4)] are the only remedies which may be granted by a court for an act of infringement described in paragraph (2). . . ." 35 U.S.C. § 271(e)(4).

[11] This section abolished traditional acts of infringement with respect to ANDAs (section 271(e)(1)), provided a new act of infringement (section 271(e)(2)) for seeking FDA approval to market generic drug products before the expiration of the applicable patents, and created a new and exclusive set of remedies for that act of infringement (section 271(e)(4)), including the availability of a court order limiting the date of FDA approval (section 271(e)(4)(A)).

Congress had wished to alter this statutory balance, it would have said so explicitly, as both FDA and the lower court recognized.

For the same reason, there is no basis for Royce's claim that the URAA contains a transitional provision whose intended beneficiary must have been the generic drug industry. Pet. at 9. If Congress had intended the transition provision to apply to the generic drug approval process (a contention flatly rejected by both the FDA and the court of appeals), it is inconceivable that it would have failed to include a specific reference to the very statutory provisions, *i.e.*, 35 U.S.C. § 271(e) and 21 U.S.C. § 355(j), it had created expressly to govern that process.

## II. THE PETITION DOES NOT PRESENT AN ISSUE OF GENERAL PUBLIC IMPORTANCE

Royce contends that the decision below will have wide-ranging consequences for other products and other parties, affecting the interests of "manufacturers of generic prescription pharmaceuticals," "the American public," and "federal, state and other third-party reimbursement programs." Pet. at 3.

While the decision below is not insignificant, both Royce and *amici* exaggerate its importance. If the issue decided below affects as many products and manufacturers as Royce and *amici* assert, it would already be the subject of a tidal wave of litigation. Significantly, however, neither Royce nor *amici* point to any other litigation. In fact, except for litigation involving Bristol's patented captopril product, there is *no* litigation (of which respondents are aware) that addresses the issue decided below.[12] The absence of

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12 Nor have any third parties (whether generic manufacturers, patented pharmaceutical manufacturers or trade associations) previously participated as *amici*, either in this case or in the *DuPont Merck* case.

comparable litigation concerning any other pharmaceutical product strongly indicates that the issue is neither as significant nor as pressing as the Petition suggests. *Compare Laing v. United States*, 423 U.S. 161, 127 (1976) (70 pending cases in federal court depended on resolution of tax conflict).

Both Royce and *amici* make the unsupported claim that the decision below affects hundreds of drugs. The current litigation position of Royce and *amici* is inconsistent with the prior claim of *amici* that the URAA would have only a minimal effect on the generic industry because "most pharmaceutical patents in effect today took longer than three years to issue. Therefore, switching to the new patent term will provide them no extension of patent term." *Chemical Marketing Reporter*, Jan. 2, 1995, at 4 (quoting Lewis Engman, President, GPIA). Moreover, the generic drug industry has publicly recognized that the result they now seek from this Court would require new legislation to amend the URAA's transition provision to close a "loophole." *See, e.g.*, 141 Cong. Rec. S6495 (daily ed. May 11, 1995) (remarks of Sen. Pryor) cited in Pet. at 9. [13] *See also* 141 Cong. Rec. S12388-12391 (August 11, 1995) (introducing S.1191 to provide that the "remedies of section 271(e)(4) . . . shall not apply to acts" that become infringing as a result of the URAA.)

Royce and *amici* also contend that this Court's review is necessary to correct the decision below which they assert contravenes the clear intent of Congress. However, the intent of Congress is determined first by reference to the

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[13] Similarly, the Corporate Counsel of one of the plaintiffs in the *DuPont Merck* case -- and a principal member of *amicus* National Association of Pharmaceutical Manufacturers -- stated in a presentation to the Food and Drug Law Institute on February 6, 1995 that:

> The GATT implementation language enacted by Congress needs immediate revision prior to its effective date of June 8, 1995.

language which Congress employed in the statute. *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). Moreover, neither Royce nor *amici* point to anything in the legislative history of the URAA that would support their claim that Congress intended to do anything other than what the plain language of the statute indicates. *Burlington Northern R.R. v. Oklahoma Tax Comm'n*, 481 U.S. 454, 461 (1987) ("[I]n the absence of a clearly expressed legislative intention to the contrary, the language of the statute itself must be ordinarily regarded as conclusive'"). In fact, the legislative history supports the lower court's construction of the URAA. Thus, the President's Statement of Administrative Action explains the scope and effect of the limitation of remedies provision of the URAA in exactly the same way in which the FDA and the lower court have construed it: "the patent owner will not be able to obtain an injunction, recover a reasonable royalty, or obtain attorneys fees *as provided for in sections 283 to 285 of Title 35*." H.R. Doc. No. 316, 103d Cong., 2d Sess. 1003 (1994) (emphasis added).

In any event, review is not appropriate because the judgment below was proper even if Royce's interpretation of the URAA's transition provision is correct (which Bristol denies and the Federal Circuit has twice rejected). The statutory "safe harbor" applies only if Royce has made a "substantial investment" in contemplation of acts which "become infringing." 35 U.S.C. § 154(c)(2). It remains to be determined whether Royce satisfies this *factual* predicate to the URAA "safe harbor." While the district court below concluded in a footnote that Royce met the statute's "substantial investment" criterion, that decision was clearly erroneous since the district court improperly accepted the factual assertions contained in an affidavit made in support of a motion to dismiss Bristol's complaint, without permitting Bristol any opportunity to take any discovery on this issue. Because the Federal Circuit found that there was no legal basis to Petitioner's claim, it did not reach the

validity of the district court's decision on the issue of "substantial investment." As a result, a decision by this Court on the issue presented by the Petition may be unnecessary and irrelevant to the disposition of the case below.

## CONCLUSION

For all of the foregoing reasons, the Court should deny the Petition.

Respectfully submitted,

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Dated: December 11, 1995

# APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

May 25, 1995

Donald O. Beers
David E. Korn
Arnold & Porter
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036

Re: Docket No. 95P-0061/CP1

Dear Messrs. Beers and Korn:

This responds to the citizen petition you submitted on behalf of Glaxo Inc. (Glaxo) dated March 7, 1995.[1] The citizen petition requests that the Food and Drug Administration (FDA) "follow the mandate of the [Uruguay Round Agreements Act (Pub. L. 103-465)] URAA in determining when approval of an Abbreviated New Drug Application ('ANDA') or application of the type described in Section 505(b)(2) of the Federal Food, Drug, and

[1] FDA has received a number of responses to Glaxo's citizen petition from generic and innovator drug manufacturers. Glaxo has submitted an additional comment on the responses dated April 13, 1995. These documents, as well as correspondence referred to in this response, are included in Docket No. 95P-0061. The agency has considered these submissions, as well as the oral and written submissions made in connection with the February 16, 1995, hearing held by the Patent and Trademark Office (PTO) at which these issues were addressed in its response to Glaxo's citizen petition.

Cosmetic Act ('FFDCA'), 21 U.S.C. § 355(b)(2), ('505(b)(2) application'), may be made effective." Citizen Petition at 1. The citizen petition specifically requests that:

(1) FDA publish patent dates as revised by the URAA in "Approved Drug Products With Therapeutic Equivalence Evaluations" (the Orange Book) prior to June 8, 1995;

(2) FDA announce that pending ANDA and 505(b)(2) applications containing paragraph III certifications to the pre-URAA patent expiration dates must be amended to acknowledge the patent expiration dates as extended by the URAA;

(3) FDA announce that any new ANDA's or 505(b)(2) applications must refer to the patent expiration dates extended by the URAA;

(4) FDA not make approvals of any ANDA or 505(b)(2) application containing a paragraph III certification effective prior to the patent expiration date as revised by the URAA; and

(5) FDA require ANDA and 505(b)(2) applicants that seek an effective date of approval prior to the URAA-revised patent expiration date to submit paragraph IV certifications for any applicable patents.

Citizen Petition at 2-3.

For the reasons set out below, the agency grants your citizen petition in part, and denies your citizen petition in part.

## I. STATUTORY AND REGULATORY BACKGROUND

The relief sought by the citizen petition filed on behalf of Glaxo must be determined under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the URAA, which establish the obligations of approved new drug application (NDA) holders, ANDA and 505(b)(2) applicants, and the agency with respect to extended expiration dates for patents covering listed drugs or their uses.[2]

### A. The FD&C Act and FDA Regulations

The agency's decision in this matter is governed by provisions of the FD&C Act related to new drug and generic drug approvals. These provisions were added to the FD&C Act through the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417) (the Waxman-Hatch Amendments). Title I of the Waxman-Hatch Amendments was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H. Rept. No. 857 (Part I), 98th Cong., 2d sess. at 14 (1984) (House Report). Title II of the Waxman-Hatch Amendments was intended to provide a new incentive for increased expenditures for research and development of drug products by "restoration of some of the time lost on patent life while the product is awaiting pre-market approval." (House Report at 15.)[3]

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2 This analysis applies as well to abbreviated new animal drug applications (ANDA's), by which manufacturers seek approval to market generic versions of animal drugs under section 512 of the FD&C Act.

3 Until the Waxman-Hatch Amendments, manufacturers of generic versions of pioneer drugs first approved after 1962 generally were required to duplicate the time-consuming and expensive safety and effectiveness studies already performed on the pioneer drugs. The

1. New Drug Applications

Under the Waxman-Hatch Amendments, pharmaceutical companies seeking to market pioneer drugs must first obtain FDA approval through the filing of an NDA (see section 505(a) and (b) of the FD&C Act). In addition to data demonstrating the safety and effectiveness of the drug, an NDA applicant is required to submit to FDA information on any patent which claims the drug or a method of using such drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party (see section 505(b)(1) and (c)(2) of the FD&C Act). The patent information must include the patent number and date of expiration. Id. If patent information is available at the time the NDA is submitted or becomes available during the pendency of FDA's review of the application, it must be included with the NDA or filed in an amendment to the application (see section 505(b)(1) of the FD&C Act).

The statute specifically anticipates that patents may issue after approval of the NDA and provides for submission of information to FDA on those patents (see section 505(c)(2) of the FD&C Act). The Waxman-Hatch Amendments provide for the extension of patent term expiration dates for listed patents under the patent term restoration provisions (see 35 U.S.C. 156).

FDA is to publish the patent information submitted to it by the NDA holder (see section 505(b)(1) and (c)(2) of the FD&C Act). The agency publishes the required patent information in its publication, the Orange Book. When accepting patent information from the NDA sponsor under

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Waxman-Hatch Amendments permit these generic drug manufacturers to rely on FDA's prior determinations of the safety and efficacy of the pioneer drug (see House Report at 14 and 15).

section 505(b)(1) and (c)(2) of the FD&C Act, FDA is acting in a solely ministerial capacity. The agency relies on the sponsor's assessment of the applicability of the patent to the drug and does not make an independent determination on that issue (see the Federal Register of October 3, 1994, 59 FR 50338 at 50343, 50345, 50348, 50349, 50361). The statutory scheme relies on private patent litigation to resolve disputes concerning patent validity and applicability (see 59 FR 50338 at 50348).

Because current patent information is an important part of the patent certification process, patent information that becomes available after approval of the NDA because of the issuance of a new patent or a Waxman-Hatch patent term extension will be published by FDA (see 59 FR 50338 at 50343).

2. ANDA's and 505(b)(2) Applications

A manufacturer that wishes to market a generic version of a pioneer drug must submit to FDA an ANDA (see section 505(a) and (j) of the FD&C Act). An applicant that wishes to gain approval of an application for a new drug when the investigations that show the safety and effectiveness of the drug were not conducted by the applicant and for which the applicant has not obtained a right of reference or use must submit to FDA a 505(b)(2) application (see section 505(a) and (b) of the FD&C Act). The statute requires that an ANDA or 505(b)(2) application contain, among other data and information, a certification with respect to each patent that claims the drug for which the ANDA applicant is seeking approval. This certification must state one of the following:

(I) that the required patent information relating to such patent has not been filed;

(II) that such patent has expired;

(III) that the patent will expire on a particular date; or

(IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

(See section 505(b)(2)(A) and (j)(2)(A)(vii) of the FD&C Act.)

The two types of patent certifications particularly relevant in this matter are those made under paragraph III (a paragraph III certification) and paragraph IV (a paragraph IV certification). A paragraph III certification indicates that the applicant does not intend to market the drug until after the expiration date of the applicable patent. An applicant whose ANDA or 505(b)(2) application contains a paragraph IV certification must give notice of the filing to the patent owner and the NDA holder for the listed drug (see section 505(b)(3) and (j)(2)(B) of the FD&C Act). This notice must include a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. Id.

FDA regulations require that an ANDA or 505(b)(2) applicant amend its patent certification if "at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate" (see 21 CFR 314.94(a)(12)(viii)(C) published at 59 FR 50338 at 50366 and 21 CFR 314.50(i)(6)(iii)(A) published at 59 FR 50338 at 50362).

3. FDA Approval of ANDA's and 505(b)(2) Applications

The timing of FDA's approval of an ANDA or 505(b)(2) application is governed, in part, by the patent certifications submitted by the applicant. FDA may approve

an application that contains a paragraph III certification on the date the patent to which the certification was made expires (see section 505(c)(3)(B) and (j)(4)(B)(II) of the FD&C Act). In the case of a paragraph IV certification, FDA will approve the application, and the approval will become effective immediately despite the unexpired patent, unless an action for infringement of the patent is brought against the applicant within 45 days of the date the patent owner and the NDA holder receive notice of the paragraph IV certification (see section 505(c)(3)(C) and (j)(4)(B)(iii) of the FD&C Act). If a patent action is brought within the 45-day period, FDA may make the approval of the ANDA or 505(b)(2) application effective no earlier (than) 30 months from the date that the patent owner and NDA sponsor received the notice, or such shorter or longer period as the court may order. Id.

B. Uruguary Round Agreements Act

The citizen petition requests that FDA "follow the mandate of the URAA" with respect to approvals of ANDA's and 505(b)(2) applications. Citizen Petition at 1. The URAA was enacted in December 1994 to implement the Uruguary Round Agreements, a series of multilateral agreements, which includes the General Agreement on Tariffs and Trade (GATT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP's).

URAA's provisions amend Title 35 of the U.S. Code to extend the period of patent protection for some patents. Section 532(a)(1) of the URAA amends 35 U.S.C. 154 to provide that patents issued after June 8, 1995 (the effective date of the patent provisions of URAA), will have a term of 20 years from the date on which the application for the patent was filed or, under certain circumstances, from the date of the earliest patent application filing. Section 532(a)(1) of the URAA also provides that, for patents in

force on June 8, 1995, or that result from an application filed before that date, the patent term shall be the greater of 17 years from the granting of the patent or 20 years from the date on which the application for the patent was filed, or under certain circumstances 20 years from the date of the earliest patent application filing.

The URAA contains a transitional provision governing acts that will become infringing due to the extension of patents in effect or already filed as of June 8, 1995. Section 532(a)(1) of the URAA limits the availability of certain statutory patent infringement remedies for acts that were commenced, or for which substantial investment was made, before June 8, 1995, and which become infringing because of the extension of the patent period.

This provision establishes that the remedies set out in sections 283, 284, and 285 of Title 35, which provide for injunctions, damages, and attorney fees, will not apply to infringing acts during this period. The URAA provides that such infringing acts may be continued upon payment of equitable remuneration to the patentee. The statute does not define "substantial investment" or "equitable remuneration."

The patent code also contains, at 35 U.S.C. 271(e)(4), a provision that establishes the remedies available for infringement of patents on drug products when a manufacturer seeks approval to market a generic version of the drug before the expiration of applicable patents. This section, which provides for a court to order that the effective date of an approval shall be no earlier than the patent expiration date, and for injunctions, damages, and attorney fees, was not among the remedial provisions explicitly made unavailable under the URAA.

Section 271(e) of Title 35 was enacted as part of Title II of the Waxman-Hatch Amendments and relates

specifically to the approval process for generic drug products.[4] Section 271(e)(1) establishes that it is not an act of infringement to use a patented drug for purposes related to obtaining regulatory approval of the product.[5] Section 271(e)(2) states that it shall be an act of infringement to submit a 505(b)(2) application or ANDA "if the purpose of such submission is to obtain approval under [the FD&C Act] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."[6] Section 271(e)(4) lists the remedies available for infringement actions brought under section 271(e)(2), and states that these will be the only remedies for a patent infringement action brought under that provision.

## II. PETITIONER'S REQUEST

Petitioner requests that FDA take five specific actions with respect to patents that have expiration dates that will be extended by the URAA. Each of these requests is discussed below.

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4 The patent term extension provisions of the Waxman-Hatch Amendments were also codified in the patent code. 35 U.S.C. 156.

5 This provision essentially overruled the court's decision in Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984) cert. denied, 469 U.S. 856 (1984), that had determined that the use of a patented product even for testing and preparing an application for regulatory approval was an act of infringement.

6 The Supreme Court has observed that section 271(e)(2) creates these "artificial" acts of infringement so that the underlying patent issue can be resolved in a court proceeding pursuant to a paragraph IV certification. Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). The Court further observes that the remedies of section 271(e)(4) are also artificial remedies. "Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." Id.

A. FDA Should Publish Patent Expiration Dates as Revised by the URAA in the Orange Book Before June 8, 1995

The Waxman-Hatch Amendments require that FDA publish the patent information submitted to it in accordance with section 505(b)(1) and (c)(2) of the FD&C Act. The agency publishes patent information submitted to FDA after approval of the NDA when the patent information derives from a patent term extension under 35 U.S.C. 156, or from the issuance of a new patent (see 59 FR 50338 at 50343).

Publication of the URAA-extended patent expiration dates in the Orange Book will assure that ANDA and 505(b)(2) applicants are aware of the patents and patent expiration dates that NDA holders believe apply to the listed drug product or use. This will permit the applicant or another interested party either to provide a corresponding certification in an ANDA or 505(b)(2) application, or to challenge the accuracy of the patent information through the procedures set out in 21 CFR 314.53(f) (published at 59 FR 50364) and 21 CFR 314.94(a)(12)(vii) (published at 59 FR 50365).

FDA denies petitioner's request that the agency publish the URAA-extended patent expiration dates before June 8, 1995. As noted in the citizen petition at p. 10, the new patent expiration dates will take effect on June 8, 1995 (see section 534 of the URAA). The agency will not accept patent information that anticipates the granting of a new patent, a situation analogous to this grant of patent term extension (see the Federal Register of July 10, 1989 (54 FR 28872 at 28908)). This position is consistent with the Waxman-Hatch Amendments' requirement that information on patents be submitted to the agency within 30 days of the date of issue, notwithstanding that patent applicants may receive advance notice that a patent will be issued (see

section 505(c)(2) of the FD&C Act). The agency has stated that, with respect to new patents, the NDA holder may informally notify the agency of the impending issuance of the patent, but that no official action will be taken in response to such notice (see 54 FR 28872 at 28908). This procedure will apply as well with respect to URAA-extended patent expiration dates.[7]

The agency expects to receive information on the URAA-extended patent expiration dates directly from the NDA holder on or after June 8, 1995.[8] The agency will place this information on public display after June 8, 1995, and will publish it in the monthly supplement to the Orange Book after June 8, 1995 (see 21 CFR 314.53(e) published at 59 FR 50364).[9]

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[7] NDA holders that have already submitted information on URAA extended patent terms should resubmit such information on or after June 8, 1995, but before July 8, 1995.

[8] The agency considers the submission of information on URAA-extended patent expiration dates to be analogous to the submission of information on newly issued patents. Information on these URAA-extended patent expiration dates should be submitted to FDA within 30 days of June 8, 1995. PTO stated in the Federal Register of March 27, 1995, that it intends to determine and publish the new expiration dates for patents that (1) will be in force on June 8, 1995, (2) that are entitled to a patent term of 20 years from the date of filing, and (3) that have received patent term extension under the Waxman-Hatch Amendments (see 60 FR 15748). PTO has indicated to FDA that it expects to publish this information before June 8, 1995.

[9] Updated information related to patents on human drug products regulated by the Center for Drug Evaluation and Research will be placed on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, under Docket No. 95S-0117, after June 8, 1995. Updated information related to patents on human drug products regulated by the Center for Biologics Evaluation and Research will be placed on public display in the Dockets Management Branch under Docket No. 95S-0135. Updated information related to patents on animal drug products will be placed on public display in the Dockets Management Branch under

B. FDA Should Announce That Pending ANDA and 505(b)(2) Applications Containing Paragraph III Certifications to the Pre-URAA Patent Expiration Dates Must Be Amended to Acknowledge the URAA-Extended Patent Expiration Dates

FDA's current regulations require that an ANDA or 505(b)(2) applicant amend its patent certification if "at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate" (see 21 CFR 314.94(a)(12)(viii)(C) published at 59 FR 50338 at 50366 and 21 CFR 314.50(i)(6)(iii)(A) published at 59 FR 50338 at 50362). After June 8, 1995, and upon timely submission by the NDA holder of the URAA-extended patent expiration dates, a pending ANDA or 505(b)(2) application that contains a paragraph III certification to the pre-URAA patent expiration date will be inaccurate under the current regulations.

Because the Waxman-Hatch Amendments and implementing regulations require that ANDA and 505(b)(2) applicants certify as to timely patent information, and that the timing of FDA's approval be governed by these certifications, the only way the agency could approve ANDA's and 505(b)(2) applications before the URAA-extended patent expiration date is if the URAA permits FDA to treat the period of extended patent protection granted by the URAA differently than it treats other patent protection asserted by NDA holders. In particular, the agency's actions depend upon whether the URAA permits FDA to make an

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Docket No. 95S-0126. Updated patent information on animal drug products will be published in the monthly supplements to "FDA Approved Animal Drug Products" (the Green Book) after June 8, 1995.

exception to the updated certification requirement for ANDA and 505(b)(2) applications. If applicants are not required to certify to the URAA-extended patent term, FDA may approve the ANDA or 505(b)(2) application upon the expiration of the pre-URAA patent term. Resolution of this issue requires FDA to make a legal judgment concerning the patent code, about which the agency has no special expertise, to determine the applicability of the transitional provisions set out within section 532(a)(1) of the URAA to the generic drug approval process.

Arguably, FDA could treat the periods of URAA-extended patent term differently than it treats other patent protection asserted by NDA holders if the URAA's transitional "grandfather" provision within section 532(a)(1) applied to infringements through ANDA submission and approval. Section 532(a)(1) of the URAA amends 35 U.S.C. 154 to limit the remedies available for infringement, permitting parties that have commenced acts, or made a substantial investment toward acts, which will become infringing under the extended patent period provided by the URAA, to market their products during the URAA-extended period upon payment of "equitable remuneration" to the patentee. The agency cannot find a basis for adopting the interpretation of the URAA that 35 U.S.C. 154, as amended, applies to infringements through ANDA submissions, which are governed by 35 U.S.C. 271(e).

The agency believes that interpretation of the interrelationship between the transitional provisions of section 532(a)(1) of the URAA and 35 U.S.C. 271(e)(4) is governed by the plain language of the URAA. The Supreme Court has established a two-step process for reviewing an agency's interpretation of a statute. Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984). Under Chevron, the first question is whether Congress has directly addressed the matter at issue. "If the

intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. at 842-43. Only if the statute is silent or ambiguous does the court turn to the second step of the Chevron analysis and determine whether the agency's interpretation of the statute is a permissible one and therefore entitled to deference. Id. at 843-44. In the present matter, the plain meaning of the URAA has determined the agency's position. See United States v. Ron Pair Enterprises, Inc., 489 U.S. 235, 241 (1989) (when language of statute is plain, it is to be enforced according to its terms). The URAA is not "silent or ambiguous" on the question of applying the transitional provision to the generic drug approval process. Indeed, if the statute did admit of more than one interpretation, FDA would have found that approval of pending applications upon the expiration of the pre-URAA patent term for patents issued before June 8, 1995, is more consistent with the underlying goals of the Waxman-Hatch Amendments.

The transitional provision of the URAA limits the remedies available to a patentee in [a] suit brought against an infringer whose actions became infringing due to the URAA patent extension. Section 532 of the URAA specifically lists the three remedial provisions that are unavailable: 35 U.S.C. 283, 284, and 285. This provision does not list among the unavailable remedies section 271(e)(4), which provides for injunctions, damages, and attorney fees for infringement actions arising from a manufacturer seeking approval from FDA to market a generic version of a patented drug product before the patent on the product expires. Moreover, this apparently is not an example of Congress having overlooked a statutory provision it might have changed had it been aware of its existence; section 533 of the URAA amends 35 U.S.C. 271(e)(4) to apply the remedies specified to a broader range of infringing actions (e.g., it extends coverage from "sale" to "offer to sell"). In light of this reference in the

URAA to section 271, the agency does not believe that it can assert that Congress was unaware of the existence of these remedies for infringement of patents on drug products, and, therefore, did not include them among the unavailable remedies in section 532(a)(1) of the URAA.

In the present matter, therefore, the plain meaning of the URAA is dispositive. While the results of this literal interpretation of the words of the statute are puzzling, in that Congress has--without explanation in the legislative history--applied the transitional "grandfathering" provision to every patented product except drugs, the agency believes that this result follows from the language of the statute.[10]

The limited legislative history for section 532 of the URAA does not provide any affirmative support for the argument asserted in responses to the citizen petition that it was Congress' intention to apply the transitional provision to all acts of patent infringement. The language in the TRIP's Agreement permits, but does not require, the inclusion of a transitional provision in the implementing legislation adopted by a member country.[11] The statements contained

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[10] The statutory language is particularly perplexing in light of recent congressional attention to health care costs, and the detrimental effect an extension of patent term protection to innovator companies may have on the availability to private and governmental consumers of lower-cost generic alternatives. These are some of the same concerns that formed a basis for passage of the 1984 Waxman-Hatch Amendments. Indeed, in a March 29, 1995, letter to Commissioner Kessler, Representative Henry Waxman, co-author of the Waxman-Hatch Amendments, notes that "applying the transition provisions to allow the more timely entry of generics onto the market is reflective of the spirit of the [Waxman-Hatch Amendments]." In contrast, Senator Orrin Hatch, also a co-author of the Waxman-Hatch Amendments, indicated in a January 19, 1995, letter to Commissioner Kessler that it is his belief that if the agency were to approve ANDA's upon the expiration of the pre-URAA patent term, it would jeopardize the "careful balance between the interests of the generic and pioneer drug manufacturers."

[11] The TRIP's Agreement provides, at Article 70.4, that:

in the Statement of Administrative Action and in the Joint Senate report are not specific as to the parties affected by the transitional provision and are merely restatements of the general technical aspects of the provision.[12]

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> In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases, the Member shall, however, at least provide for the payment of equitable remuneration.

(Emphasis added.) Reprinted in H. Doc. No. 316, 103d Cong., 2d sess. at 1651-1652 (1994) (House Document).

[12] The Statement of Administrative Action that accompanied the URAA states that:

> Section 532(a) also adds sections 154(c)(2) and (3) [to the patent code]. These sections address situations where a third party begins use of a patented invention before the date that is six months after the date of enactment of the Uruguay Round Agreements Act and such use becomes infringing because of a change in patent term due to operation of section 154(c)(1). In such circumstances, the patent owner will not be able to obtain an injunction, recover a reasonable royalty, or obtain attorneys fees as provided for in sections 283 to 285 of Title 35, but will be able to recover equitable remuneration from a third party who infringes the patent during the period in question.

House Document at 1003.

The Joint Report of the Committee on Finance, Agriculture, Nutrition, and Forestry, and Governmental Affairs contains a nearly identical statement:

> Section 532(a) adds new sections 154(c)(2) and (3). These sections address the situation where a third party begins

In a May 19, 1995, letter to Commissioner Kessler, United States Trade Representative Kantor, chief negotiator of the Uruguay Round Agreements, indicated that the intention of the language of the provision was to treat all companies equally. In other words, according to the United States Trade Representative, generic pharmaceutical companies that have made a substantial investment in anticipation of the expiration of the pre-URAA patent should be permitted to market their products as of that date, upon payment of equitable remuneration. This letter indicates that the language of the URAA does not reflect the legislative intent. Nevertheless, the language of the statute is controlling.

For the reasons set out above, the agency has determined that the URAA provides no basis for FDA to treat the period of patent extension furnished by the URAA differently than it treats other patent protection asserted by NDA holders. There is therefore no support for FDA to change its regulation that requires an applicant with a pending ANDA or 505(b)(2) application to amend its certification to respond to patent information filed after the application was submitted but before approval is effective. ANDA and 505(b)(2) applications pending before the agency on June 8, 1995, that contain certifications only with respect to pre-URAA patent expiration dates must be amended to

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using a patented invention anytime during the six months after the enactment of the legislation and such use becomes infringing because of a change in patent term due to the operation of section 154(c)(1). In such circumstances, the patent owner will not be able to obtain an injunction, recover a reasonable royalty, or obtain attorneys fees, but will be able to recover equitable remuneration.

S. Rept. No. 412, 103d Cong., 2d sess. at 228-229 (1994).

respond to URAA-extended patent expiration dates, if such information is submitted in a timely manner by the NDA holder. Applications that do not include certifications amended to respond to the URAA-extended patent expiration dates will not be approved.

C. FDA Should Announce That Any New ANDA's or 505(b)(2) Applications Must Refer to the Patent Expiration Dates Extended by the URAA

The agency has determined that the URAA-extended patent expiration dates submitted to FDA in a timely manner by the NDA holder will be the applicable patent expiration dates with respect to patent certifications under section 505(j)(2)(A)(vii) and (b)(2)(A) of the FD&C Act. This determination applies to new ANDA's and 505(b)(2) applications submitted to FDA after the effective date of the URAA patent extension provisions, as well as to applications pending before the agency on the effective date.

D. FDA Should Not Make Approvals of Any ANDA or 505(b)(2) Application Containing a Paragraph III Certification Effective Before the Patent Expiration Date as Revised by the URAA

As discussed above, the timing of FDA approval of an ANDA or 505(b)(2) application is governed in part by the patent certifications submitted by the applicant. In the case of a paragraph III certification, FDA will make approval of the application effective no earlier than the expiration date of the patent that is the subject of the paragraph III certification. Further, FDA regulations require that an applicant with a pending ANDA or 505(b)(2) application amend the certification to respond to timely patent information--including URAA patent extension

information--filed with the agency after the ANDA was submitted. If an application contains a paragraph III certification only with respect to the pre-URAA expiration date for the patent, FDA will not approve the application because the ANDA or 505(b)(2) application will not contain a certification to patent information submitted by the NDA holder in a timely fashion (see section 505(d)(6) and (j)(3)(J) of the FD&C Act).

E. FDA Should Require ANDA and 505(b)(2) Applicants that Seek an Effective Date of Approval Before the URAA-Revised Patent Expiration Date to Submit Paragraph IV Certifications for Any Applicable Patents

The drug approval process established by the Waxman-Hatch Amendments requires that an ANDA or 505(b)(2) application contain a certification stating the status of patents submitted to FDA by the NDA holder. The only certification that is appropriate if an applicant wishes to challenge such a patent is a paragraph IV certification. The paragraph IV certification is appropriate when the applicant believes that the listed patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (see section 505(b)(2)(A)(iv) and (j)(2)(A)(vii)(IV) of the FD&C Act). A paragraph IV certification is also appropriate when an applicant believes that the patent is unenforceable (see 21 CFR 314.94(a)(12)(i)(A)(4) published at 59 FR 50338 at 50365, 21 CFR 314.50(i)(1)(i)(A)(4) published at 59 FR 50338 at 50361, and 59 FR 50338 at 50339 (discussing Merck v. Danbury Pharmacal, Inc., 694 F. Supp. 1 (D. Del. 1988), aff'd, 873 F.2d 1418 (Fed. Cir. 1989))).

FDA cannot require an ANDA or 505(b)(2) applicant to file a paragraph IV certification with respect to a patent. It can, and will, however, refuse to approve an application that

contains a paragraph III certification to an incorrect patent expiration date, including a certification to the pre-URAA expiration date of a patent for which a URAA-extended patent expiration date has been submitted to the agency in a timely fashion. If an applicant with an incorrect certification wishes to obtain FDA approval of its ANDA or 505(b)(2) application, it must amend its application to provide either a paragraph III certification indicating that it will wait until the URAA-extended patent has expired, or a paragraph IV certification indicating that the patent is invalid, unenforceable, or will not be infringed. As discussed above, if a patent challenge is brought within 45 days by the patent owner or NDA holder, FDA must stay its approval for at least 30 months, unless a shorter or longer time is ordered by a court.[13]

## III. CONCLUSION

The 1984 Waxman-Hatch Amendments to the Federal Food, Drug, and Cosmetic Act represent a careful balance between the policies of fostering the availability of generic drugs and of providing sufficient incentives for research on breakthrough drugs. This landmark compromise between the interests of the generic drug companies and the pioneer companies was intended to grant a one-time patent term extension in exchange for the prompt availability of generic drug products. There is certainly a strong argument to be made that such a compromise should not be upset without hearings and careful deliberation as to the impact on the twin interests served by the Waxman-Hatch Amendments.

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[13] The agency is aware that for some applicants, the 30-month stay required of FDA will consume whatever period of marketing the applicant might have gained by obtaining approval upon the expiration of the pre-URAA patent term.

Here there were neither hearings nor a single word of debate on the floor of the House or Senate on the impact of the URAA on the 1984 Waxman-Hatch Amendments. Nor do the committee reports indicate that Congress understood that the URAA would both grant a patent term extension for certain pioneer products and block FDA from approving generic versions of those drugs until the extended patent terms have expired. Nonetheless, the language of the URAA directs that result.

Accordingly, for the reasons stated above, FDA grants your citizen petition in part and denies your citizen petition in part. FDA has determined that the URAA-extended patent term expiration dates will be the governing patent expiration dates with respect to NDA submissions and FDA publication of patent information on listed drugs and their uses; however, FDA will not publish the URAA-extended patent expiration dates until after they become effective on June 8, 1995. ANDA's and 505(b)(2) applications pending before the agency on June 8, 1995, must be amended to respond to the URAA-extended patent expiration dates, if information on the new expiration dates is submitted to the agency in a timely manner. ANDA's and 505(b)(2) applications submitted after June 8, 1995, similarly must provide patent certifications with respect to the URAA-extended patent expiration dates. After June 8, 1995, FDA will not approve any application that does not contain a correct certification with respect to a URAA-extended patent expiration date that was submitted in a timely manner to the agency. Finally, FDA cannot require that an applicant submit a paragraph IV certification as to a certain patent. The agency expects that an ANDA or 505(b)(2) applicant that wishes to market a generic version of a drug prior to the expiration of a URAA-extended patent, for which

information was timely submitted to FDA, will file a paragraph IV certification with respect to that patent.

Sincerely yours,

/s/William B. Schultz
Deputy Commissioner for Policy